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Document Processing Desk (DCI/PRD)
Office of Pesticide Programs (7508P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

Attn: Ms. Margaret Hathaway

Subject: Thiamethoxam Registration Review
Chemical Number - 060109
ID# GDCI-060109-1308

Dear Ms. Hathaway:

Syngenta Crop Protection, LLC herein is submitting comments to the EPA Neonic Planning Mitigation Outline – Thia 3-26-19 COB

I) Human Health Risk Management Proposal

Occupational Handler – Seed Treatment

Proposed PPE:

Syngenta Response: EPA did not take into account the volume restrictions for corn. Provided volume restrictions remain as written on Cruiser 5FS label, and are added to all Cruiser corn seed treatment labels, respirator and additional closed system restrictions unnecessary.

1. Double layer + gloves + respirator
   a. Corn (field) – multiple activities
   b. Corn (sweet) – mixer/loader

Syngenta response: Respirator not required due to gallon restriction.

Require Closed Loading System:

1. Corn (popcorn) – multiple activities and mixer/loader
2. Corn (sweet) – multiple activities

Syngenta Response: Closed system not required due to gallon restriction.

Occupational Handler – Liquid/Foliar Spray Application

Proposed PPE:

1. Add gloves
   a. Mixing loading liquids for aerial application, field crop high acreage
   b. Mixing/loading/applying dry flowable formulations with a manually-pressurized handwand, poultry/livestock house/horse barn/feed lot
   c. Mixing/loading/applying liquids with a manually-pressurized handwand, warehouse - C&C
   d. Mixing/loading/applying dry flowable formulation with manually-pressurized handwand, mounds/nests
   e. Mixing/loading/applying liquids with a manually-pressurized handwand, childcare center/schools/institutions – C&C
   f. Mixing/loading/applying DF formulations with a mechanically-pressurized handgun, landscaping, trees/shrubs/bushes
   g. Mixing/loading/applying liquids with a manually-pressurized handwand, mounds/nests
   h. Mixing/loading/applying liquids with a manually-pressurized handwand, residential living spaces (homes, apartments) - C&C
2. Add gloves + respirator –

a. Mixing/loading DF formulations for aerial application, sod
b. Mixing/loading DF formulations for aerial application, field crop high acreage
c. Mixing/loading/applying liquids with a mechanically-pressurized handgun, warehouse

Syngenta Response: Syngenta agrees with the Agency's proposed mitigation.

II) For the Honey Bee Ecological Risk Management Proposal – Syngenta would like to provide the following:

Please see ADDENDUM 1 – Bee Risk Management Information for Foliar and Soil Applications

Restrict Neonicotinoid use to a single a.i. per year per crop (applies to all neonics for all uses) - Syngenta recommended to EPA in our meeting on 4/3/19 that PRD should reach out to grower groups to understand the potential impact of this proposal. EPA stated that they are working with citrus growers. Syngenta provided to National Cotton Council contact information for EPA/PRD. Syngenta provided to the American Soybean Association contact information for EPA/PRD. Other issues include: (1) this proposed restriction poses potential legal issues and concerns; (2) this proposed restriction raises potential implementation and enforceability issues and concerns; (3) if the product does not perform at the level needed for efficacy control, the grower could not switch to another neonic, etc.

Root and Tuber (Sweet Potato Only - only pollinator attractive crop)

Proposed EPA Mitigation:
Foliar Applications: Prohibit use vining to harvest.
Soil Applications: Prohibit use vining to harvest.

Proposed Syngenta Mitigation:
Foliar Applications: For sweet potatoes (flowering varieties only), do not apply after the appearance of the initial flower buds until after petal fall is complete.

Soil Applications: For flowering sweet potato varieties only, do not apply after 30 days after planting, regardless of application method

According to NCSU personnel, not all sweet potato varieties flower; if they do, it is most commonly later in the growth cycle of a 90-150 day crop. Many soil applications in sweet potatoes are made during the actual planting/transplanting operation, but also at hilling or layby operations. A 30 day window provides flexibility to apply at hilling or layby, but still provides a significant pre-bloom period.

Fruiting Vegetables

Proposed EPA Mitigation (for tomatoes, peppers, chili peppers and okra only):
Foliar Applications: Pre-bloom application timing restriction.
Soil Applications: Pre-bloom application timing restriction.

Proposed Syngenta Mitigation:
Foliar Applications: Do not apply after the appearance of the initial flower buds.

Fruiting vegetables continue to flower throughout their life cycle once they begin. Appearance of the very first flower buds is likely the best visual indicator to stop making foliar applications of thiamethoxam. Stopping applications at the onset of flower buds will reduce the amount of thiamethoxam translocated to pollen and nectar when the crop is in full bloom.

Soil Applications: Do not apply after 5 days after planting or transplanting regardless of application method.

Many soil-applied applications are made during the actual planting/transplanting operation, but some are made post-planting as described on the Platinum label. A 5 day window provides flexibility to apply post-planting (eg. through the drip tape), but still provides a significant pre-bloom period in a 65-80 day crop.

Cucurbits

Proposed EPA Mitigation:
Foliar Applications: Prohibit use vining to harvest.
Soil Applications: No mitigation.

Proposed Syngenta Mitigation:
Foliar Applications: Do not apply after the appearance of the initial flower buds.

Cucurbit vegetables continue to flower throughout their life cycle once they begin. Appearance of the very first flower buds is likely the best visual indicator to stop making foliar applications of thiamethoxam. Stopping applications at the onset of flower buds will reduce the amount of thiamethoxam translocated to pollen and nectar when the crop is in full bloom.

Soil Applications: No mitigation

Pome Fruit

Proposed EPA Risk Mitigation:
Foliar Applications: Prohibited from green/silver tip stage through bloom.

Proposed Syngenta Mitigation:
Foliar Applications:

- Apple: Do not apply from the silver tip stage until after petal fall is complete.
- Pear: Do not apply from swollen bud stage until after petal fall is complete.

Stone Fruit

Proposed EPA Mitigation:
Foliar Applications: Prohibit pre-bloom foliar application.

Proposed Syngenta Mitigation:
Foliar Applications: Do not apply prior to bloom or until after petal fall is complete.

Berries and Small Fruits

Proposed EPA Mitigation (Non-Grapes):
Foliar Applications:

- Prohibit pre-bloom foliar application, except strawberries.
- Strawberries – reduce maximum annual application rate.

Soil Applications (all non-grape uses):

- Reduce maximum annual application rate.

Proposed Syngenta Mitigation (Non-Grapes):

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Foliar Applications:

- Syngenta advised EPA that these are minor crop uses, so data was generated by IR4. Syngenta provided IR4 contact information for EPA/PRD for further discussion/determination if reducing maximum annual application rate is feasible based on grower needs.
- Do not apply from swollen bud stage until after petal fall is complete, for berries and small fruits except strawberries.
- For strawberries - do not exceed a total of 8.0 oz of Actara (0.125 lb ai) per acre per year. In addition, do not exceed a total of 0.125 lb ai of any foliar-applied thiamethoxam-containing products per acre per year. Do not use Actara in the same year thiamethoxam is used as a soil application

Tree Nuts

Proposed EPA Mitigation:
Foliar Applications (pre-bloom):

- For walnuts and pecans, restrict application after bud break.
- For other tree nuts crops, prohibit pre-bloom application.

Proposed Syngenta Mitigation:
Foliar Application:

- For walnuts and pecans - Do not apply prior to bud break or until after petal fall is complete.
- For other tree nut crops - Do not apply prior to bloom or until after petal fall is complete.

Cotton

Proposed EPA Risk Mitigation:
Foliar Applications: Prohibit application at first appearance of candle crop stage.

Proposed Syngenta Mitigation:
Foliar Applications: Do not apply after candle stage or during bloom if managed bee hives are known to be within 500 feet of the field location. Wait at least 10 days after application before placing beehives in or near the treated field.

Tropical and Subtropical Fruit

Proposed EPA Mitigation -

- Foliar Applications: Reduce maximum annual application rate.

Proposed Syngenta Mitigation:

- Syngenta advised EPA that these are minor crop uses, so data was generated by IR4. Syngenta provided IR4 contact information for EPA/PRD for further discussion/determination if reducing maximum annual application rate is feasible based on grower needs.

Turf (not sod)

Mitigation for All Uses:

- Add advisory language to recommend maintaining lawns to minimize flowering plants and weeds prior to application.
- Pollinator advisory language currently on some but not all labels.

Proposed Syngenta Mitigation:

- Syngenta agrees with this risk mitigation

Ornamentals

Restrict use to certified applicators or those under their direct supervision.

Includes: Ornamental ground cover, Christmas tree plantations, Ornamental and/or shade trees, ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines, greenhouse use.

- Add advisory pollinator language already currently on some but not all labels.

Acute Risk Mitigation:

- Maintain current at-bloom application prohibition.

Chronic Risk Mitigation:

- Foliar Applications: Prohibit application to pollinator attractive plants (this restriction excludes forestry uses).
- Soil Applications: Prohibit application to pollinator attractive plants (this restriction excludes forestry uses).
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Proposed Syngenta Mitigation:

- The EPA label review manual allows the PM/team leader, if determined that additional label language could mitigate use, to propose alternative labeling language. In lieu of assigning thiamethoxam as a restricted use active ingredient when applied outdoors to ornamental plants, it is proposed that product labels contain this (or similar) statement: "This product is not intended for use by home applicators". Most recently, EPA has proposed a label use statement as a mitigation driven by ground water concerns of pymetrozine. It may be found in EPA's 'Pymetrozine – Proposed Interim Registration Review Decision – Case Number 7474. December 2018.

III) Terrestrial (Non-Pollinator) Ecological Risk Management Proposal

Seed Treatments: Add advisory language directing applicators to clean up spills, dispose of excess seed to avoid contamination of water bodies, *e.g.*:

"Cover or collect treated seeds spilled during loading and planting in areas (such as in row ends)."
"Dispose of all excess treated seed by burying seed away from bodies of water."
"Do not contaminate bodies of water when disposing of planting equipment wash water."

Syngenta Response: EPA will investigate whether these restrictions are only required for the seed tag section of the seed treatment label and required to be repeated in another section of the seed treatment, as well.

IV) Aquatic Invertebrate Ecological Risk Management Proposal

General Mitigation: Spray Drift

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1) Applies to all foliar spray applications
    a. Require buffers to aquatic water bodies on all labels
        i. 25 feet ground, 150 feet aerial; 10 feet* vegetative filter strip (*for runoff)
    b. Specify spray droplet size of medium or coarser (ASABE S572.1)
    c. Maximum wind speed of 15 mph
    d. Maximum boom height of 4 feet for ground application
    e. Maximum of 10 feet above the vegetative canopy for aerial application, unless a greater application height is necessary for pilot safety.
    f. For aerial application at wind speeds over 10 mph, maximum boom length 65% wingspan (fixed) 75% (rotor)

Syngenta agrees with the proposed label mitigation measure, with the following exception for turf labels only: As turf is inherently a level, well-maintained vegetative filter strip, Syngenta requests that turf labels be exempted from the 10 foot vegetative filter strip language requirement.

General Mitigation: Runoff

1) Applies to outdoor non-agricultural uses
    a. Establish label consistency by requiring revisions to general labeling for spot treatments, crack and crevice treatments, and band and perimeter treatment
        i. Band/Perimeter treatment must specify area of application (ft) around buildings or structures both horizontally and vertically
        ii. Spot treatments must specify area of application (sq. ft)
        iii. Do not apply to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack and crevice treatment
        iv. Do not apply to the point of runoff
    b. Establish label consistency by requiring rainfall advisories
        i. Advisory language to not apply during rainfall or when rain is expected within 24 hours – exception for products requiring watering in
    c. Label clarifications
        i. Specify whether products are for use indoors or outdoors

Syngenta Response: Syngenta agrees with the proposed mitigations. Proposed language for band/perimeter treatments: For perimeter band applications: Apply just enough product to be effective but in a band of no more than a total of 7 feet in width, including a distance of no more than 2 feet up the exterior wall and no more than 5 feet out on the horizontal substrate away from the wall base. If landscape plantings or other stationary obstructions prevent direct application within the 7 foot band, move up the wall and/or away from the wall base only as far as needed to effectively complete the perimeter application.

Syngenta Crop Protection, LLC appreciates the opportunity to provide this information to the Agency on The Registration Review Mitigation Proposal for Thiamethoxam – 3/26/19. Please feel free to contact me at 336-632-2446 or via email at Charles.levey@syngenta.com.

Respectfully yours,

Charles T. Levey
Federal Team Lead
Syngenta

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ADDENDUM 1 - Bee Risk Assumptions and Uncertainty

EPA's pollinator risk assessment is based not only on field-derived measures of exposure from crop-specific pollen/nectar residue studies but also on effects studies, including the colony feeding studies, that may not be indicative of actual field exposures. Measured residues in pollen/nectar represent residue levels that are worst-case for individual bee exposure rather than colony-level exposure. In addition, the colony feeding study (CFS) represents an exposure scenario where a colony is getting the majority of its nectar from a crop over at least a 6-week period. Very few crops listed as potential concern by EPA would fall under this highly conservative exposure scenario where the nectar and pollen from the crop would represent the majority of pollen/nectar consumed over an extended duration. Two of the crop groups listed as high potential risk, cotton and fruiting vegetables, are only considered moderately attractive to honey bees and/or non-*Apis* bees or are attractive to bees only under certain conditions (USDA 2017)[1]. Regrettably, the risk assessment process does not quantitatively account for attractiveness of the crop to honey bees in estimating colony level exposure. Therefore, risk conclusions from this assessment represent "potential risks" to bees and not necessarily adverse impacts that are occurring from use of thiamethoxam under actual field conditions. Data from the open literature that include in-hive residue levels demonstrate a lack of widespread exposure to thiamethoxam at concentrations expected to result in colony-level effects. In addition, available field and/or incident data show little evidence of colony-level effects from labeled use of neonicotinoids including thiamethoxam.

Acknowledging these assumptions and risk assessment uncertainties, Syngenta supports EPA's efforts in providing a tiered, science-based risk assessment process for thiamethoxam and the other nitro-guanidine neonicotinoids. The potential risks identified in the preliminary risk assessment are based on pollen and nectar residue data exceeding a scientifically robust colony level effects endpoint. Syngenta, along with the Neonicotinoid Consortium, agree on general principles for managing potential risks to bees as supported by the available pollen and nectar data for foliar and soil applications

Foliar Applications

For foliar applications, potential risk to bees can be mitigated in many crops via timing of applications. Specific label restrictions regarding timing of foliar applications necessary to manage potential risks to bees will likely vary among crops and chemicals. Decisions should be guided by scientific data as well as consideration of grower practices and benefits of the uses under evaluation. Review of the pollen and nectar residue data from pre-bloom applications clearly indicate that residues decline rapidly after application with a DT50 of approximately 3 days for pollen and 4 days for nectar (Figure 1). In addition, many of these studies were conducted using more than one application prior to bloom with short intervals between applications (i.e., 5 to 7 days) resulting in higher maximum residues than what would be present with just a single application.

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[1] USDA (2017). Attractiveness of Agricultural Crops to Pollinating Bees for the Collections of Nectar and/or Pollen.
https://www.ars.usda.gov/ARSUserFiles/OPMP/Attractiveness%20of%20Agriculture%20Crops%20to%20Pollinating%20Bees%20Report-FINAL_Web%20Version_June%202017.pdf

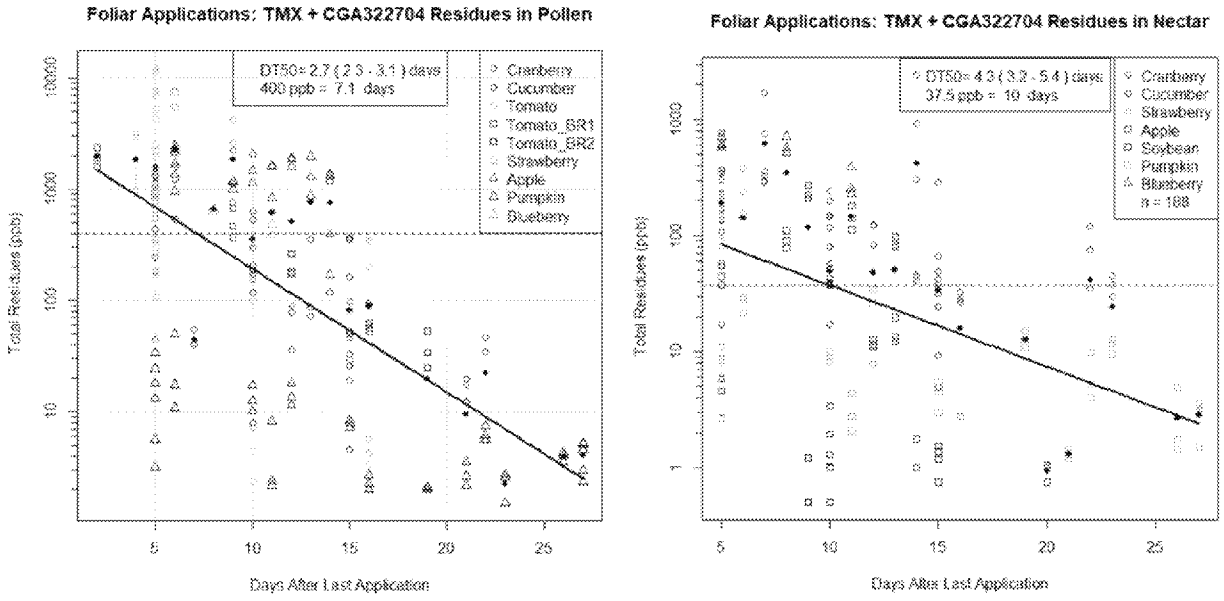

Figure 1. Aggregate Data Analysis of Pollen and Nectar Residues from Pre-Bloom Foliar Applications

In addition, a common misconception concerning foliar applications of thiamethoxam and other neonicotinoids is that thiamethoxam enters leaf tissue and moves systemically throughout the plant. While thiamethoxam can readily move via xylem from the roots to the tips of the plants and is the basis for plant protection using seed treatments and soil treatments, for foliar treatments, thiamethoxam is much less mobile (i.e., not phloem-mobile) and foliar applications have a shorter pest control duration than soil or seed treatments (although foliar is more effective for direct contact and residual contact control). Thiamethoxam in pollen and/or nectar from pre-bloom and post-bloom foliar applications most likely comes from the direct spraying of developing flower bud or dormant bud tissue. Therefore, timing of foliar applications to prevent or limit spraying of developing flower bud tissues will reduces residue levels in pollen and nectar.

Soil Applications

For soil applications, potential risk to bees is considered minimal to moderate and risk can be managed by adjusting application timing and planting density. Decisions should be guided by scientific data as well as consideration of grower practices and benefits of the uses under evaluation.

In general, pollen and nectar residues from crops treated with soil applications are highly variable within each crop group. Many factors can influence pollen and nectar concentrations including application type (drench versus drip), application rate and timing, soil type (coarse versus fine soils) and planting density (plants per hectare). Mitigations based on soil type, application rate or planting density (i.e., application rate per plant) should be considered as opposed to eliminating soil uses entirely, particularly for crops that have no other or limited plant protection options (e.g., whitefly vectored plant viruses in vegetables) or concerns about pest resistance.